

**Legislative Overview for
Personalized Medicine Coalition
112th Congress**

Regulatory Policy Legislation

S. 1700: Medical Device Regulatory Improvement Act

Sponsors: Sen. Amy Klobuchar (D-MN), Sen. Richard Burr (R-NC), and Sen. Michael Bennet (D-CO)

Summary: To reduce some of the regulatory authority of the Food and Drug Administration's Center for Devices and Radiological Health, ease conflict-of-interest rules and require agency officials to contract with an outside reviewer to evaluate the work of the center.

Status: October 13, 2011 - Introduced and referred to the Committee on Health, Education, Labor, and Pensions.

H.R. 3205: The FDA Renewing Efficiency From Outside Reviewer Management (REFORM) Act

Sponsors: Rep. Erik Paulsen (R-3rd MN) and Rep. Altmire (D-4th PA)

Summary: FDA currently uses third parties to review device applications and conduct inspections, but FDA's utilization of third parties could be improved and increased. This act would improve the third-party review program to foster better participation in the program, which would decrease premarket clearance times and conserve valuable FDA resources. This bill also would reauthorize the third party inspection program.

Status: October 14, 2011 - Introduced and referred to the Committee on Energy and Commerce.

Committee on Energy and Commerce FDA Reform Package

H.R. 3205 is one of ten bills introduced October 14, 2011 by the House Energy and Commerce Committee, after hearing from patients, inventors, investors, and employers, to improve the predictability, consistency, and transparency of FDA's medical device review and approval process.

- **H.R. 3209: Premarket Predictability Act**
Sponsor: Rep. John Shimkus (R-19th IL)
- **H.R. 3203: Novel Device Regulatory Relief Act**
Sponsor: Rep. Brian Bilbray (R-50th CA)
- **H.R. 3230: Keeping American Competitive through Harmonization Act**
Sponsor: Rep. Cathy McMorris Rodgers (R-5th WA)
- **H.R. 3205: FDA Renewing Efficiency From Outside Review Management Act**
Sponsor: Rep. Erik Paulsen (R-3rd MN)
- **H.R. 3211: Humanitarian Device Reform Act**
Sponsor: Rep. Charles Bass (R-2nd NH)
- **H.R. 3208: Patients Come First Act**
Sponsor: Rep. John Shimkus (R-19th IL)
- **H.R. 3206: Cultivating Scientific Expertise to Foster Innovation Act**
Sponsor: Rep. Michael Burgess (R-26th TX)
- **H.R. 3214: Food and Drug Administration Mission Reform Act**
Sponsor: Rep. Michael Rogers (R-8th MI)
- **H.R. 3207: Modernizing Laboratory Test Standards for Patients Act (see below)**
Sponsor: Rep. Michael Burgess (R-26th TX)

- **H.R. 3204:** Guidance Accountability and Transparency Act
Sponsor: Rep. Brett Guthrie (R-2nd KY)

H.R. 3207: Modernizing Laboratory Test Standards for Patients Act

Sponsor: Rep. Michael Burgess (R-TX)

Summary: Last year, FDA announced that it intended to regulate all Laboratory Developed Tests, which are tests that are developed within labs and which are not sold by the laboratories as medical devices.³⁵ FDA decided to take this approach despite the fact that these Lab Developed Tests are already extensively regulated under a separate approach, called Clinical Lab Improvement Amendments (CLIA), which is administered by the Centers for Medicare and Medicaid Services. There is concern that this will create unnecessary and costly regulatory duplication. The Modernizing Laboratory Test Standards for Patients Act would clarify that FDA does not have authority over Lab-Developed Tests and Direct-to-Consumer Tests. Further, it would add safety protections for patients.

Status: October 14, 2011 – Introduced and referred to the Committee on Energy and Commerce.

Intellectual Property

S. 23/H.R. 1249: America Invents Act [Patent Reform Act]

Sponsor: Rep. Lamar Smith (R-21st TX)

Summary: Changes the patent application system from one that awards patents to the first person to invent something to a system that awards the first person to file a patent application on an invention. It would also allow for more public feedback on applications in order to prevent bad patents, establish new rules for challenging patents, guarantee that fees from patent applications can be retained by the patent office, and more.

Directs the Under Secretary of Commerce for Intellectual Property and the Director of the United States Patent and Trade Office to:

- (1) The impact that the current lack of independent second opinion testing has had on the ability to provide the highest level of medical care to patients and recipients of genetic diagnostic testing, and on inhibiting innovation to existing testing and diagnoses.

- (2) The effect that providing independent second opinion genetic diagnostic testing would have on the existing patent and license holders of an exclusive genetic test.

- (3) The impact that current exclusive licensing and patents on genetic testing activity has on the practice of medicine, including but not limited to: the interpretation of testing results and performance of testing procedures.

- (4) The role that cost and insurance coverage have on access to and provision of genetic diagnostic tests.

(c) **Confirming Genetic Diagnostic Test Activity Defined-** For purposes of this section, the term ‘confirming genetic diagnostic test activity’ means the performance of a genetic diagnostic test, by a genetic diagnostic test provider, on an individual solely for the purpose of providing the individual with an independent confirmation of results obtained from another test provider’s prior performance of the test on the individual.

Status: June 23, 2011, passed the House 304-117. September 7, 2011, passed the Senate 89-9. **Signed into law September 15, 2011.**

Health Reform

S. 660: Preserving Access to Targeted, Individualized, and Effective New Treatments and Services (PATIENTS) Act

Sponsor: Senator Jon Kyl (R-AZ), and five Republican cosponsors

Summary: A bill to protect all patients by prohibiting the use of data obtained from comparative effectiveness research to deny or delay coverage of items or services under Federal health care programs and to ensure that comparative effectiveness research accounts for advancements in personalized medicine and differences in patient treatment response.

Status: March 29, 2011 – Introduced and referred to the Senate Health, Education, Labor and Pensions Committee.

H.R. 556: Preserving Patients' Choices Act

Sponsor: Rep. Thaddeus McCotter (R-11th MI)

Summary: To repeal certain provisions in the Patient Protection and Affordable Care Act related to patient centered outcomes research and rescind unobligated appropriations related to such provisions and to repeal certain health care-related provisions in the American Recovery and Reinvestment Act of 2009 and rescind unobligated appropriations related to such provisions for purposes of reducing the national debt.

Status: February 15, 2011, referred to the House Committee on Energy and Commerce, Subcommittee on Health.

S.17: Medical Device Access and Innovation Protection Act

Sponsor: Sen. Orrin Hatch (R-UT), Cosponsors: Sen. Burr (R-NC) and 10 (R) others.

Summary: SEC. 2. REPEAL OF MEDICAL DEVICE EXCISE TAX.

Subsections (a), (b), and (c) of section 1405 of the Health Care and Education Reconciliation Act of 2010, and the amendments made thereby, are hereby repealed; and the Internal Revenue Code of 1986 shall be applied as if such section and amendments had never been enacted.

Status: January 25, 2011 - Introduced and referred to the Senate Committee on Finance.

S. 248: Empowering States to Innovate Act

Sponsor: Senator Ron Wyden (D-OR), Cosponsors Sen. Scott Brown (R-MA) and Mary Landrieu (D-LA)

Summary: SEC. 2. Earlier Start for State Health Care Coverage Innovation Waivers.

Section 1332(a) of the Patient Protection and Affordable Care Act is amended--

(1) by striking 'January 1, 2017' in paragraph (1) and inserting 'January 1, 2014'; and

(2) by inserting 'beginning not later than 180 days after the date of the enactment of the

Empowering States to Innovate Act' after 'application' in paragraph (4)(B)(ii).

Status: February 1, 2011-Introduced and referred to the Senate Committee on Health, Education, Labor, and Pensions.

H.R. 105: Small Business Health Fairness Act

Sponsor: Rep. Dan Horton (R-5th IN)

Summary: To repeal the Patient Protection and Affordable Care Act and related health-care provisions and to enact in its place incentives to encourage health insurance coverage, and for other purposes.

Comparative Effectiveness Research provisions:

SEC. 801. (a) the Secretary of Health and Human Services –

(1) shall not use data obtained from the conduct of comparative effectiveness research, including such research that is conducted or supported using funds appropriated under the American Recovery and Reinvestment Act of 2009, to deny coverage of an item or service under a Federal health care program; and

(2) shall ensure that CER conducted or supported by the Federal Government accounts for factors contributing to differences in the treatment response and treatment preferences of patients, including patient-reported outcomes, genomics and personalized medicine, the unique needs of health disparity populations, and indirect patient benefits.

Status: February 1, 2011- Referred to House Committee on Energy and Commerce.

H.R. 2/S. 192: Repealing the Job-Killing Health Care Law Act

Sponsor: Rep. Eric Cantor (R-7th VA) and 182 co-sponsors/Sen. Jim Demint (R-SC) and 39 co-sponsors

Summary: Repeals the Patient Protection and Affordable Care Act, effective as of its enactment. Restores provisions of law amended by such Act. Repeals the health care provisions of the Health Care and Education and Reconciliation Act of 2010, effective as of the Act's enactment. Restores provisions of law amended by the Act's health care provisions.

Status: January 19, 2011 - Passed the House 245-189. January 26 - Placed on Senate Legislative Calendar.

Draft Legislation

Modern Cures Act

Summary: From Discussion Draft

Sponsor: Rep. Leonard Lance (R-NJ) [Expected]

MODDERN would help doctors find the patients most likely to be helped by a certain treatment by offering more tests to doctors and patients.

Right now, there's no clear pathway for getting new tests approved. Plus, once approved, it can still take a year or more before a test is available for patients. MODDERN will open a clear pathway for approving new tests.

The MODDERN Cures Act will:

- Create a new class of drugs. This will include drugs that were ignored or set aside in the lab. Some of these drugs hold the promise to treat diseases with few or no medical options. They would be known as "dormant therapies."
- Encourage drug companies to study these promising treatments. The focus would be on drugs that slow down or prevent disease.
- Make it easier to predict if a test will get approved before investing in it.
- Ensure that Medicare will reimburse for these tests and treatments.
- Get quicker access to tests for those in need.

Status: Not yet introduced

BETTER Patient Care Act

Summary: From Confidential Draft, Not for Distribution

- The bill establishes a new category of regulated products, "In Vitro Diagnostic Products ('IVDP') distinct from a "medical device," under Section 201(h) of the Federal Food, Drug and Cosmetic Act (FDCA), Subchapter G;
- Creates a regulatory framework within the FDA that divides IVDPs into high, moderate, and low risk tests and establishes a 'fast track' process including accelerated approval and priority review.
 - Permits laboratory developed tests (LDTs) and IVDPs already commercialized to remain in clinical use under certain circumstances, including if those performed in a CLIA laboratory, so long as it has been cleared or approved by the state of New York CLEP.
- Defines 'competent and reliable scientific evidence' as that evidence that substantiates intended use claims, have been conducted and evaluated in an objective manner by qualified persons, using procedures generally accepted by others in the profession;
 - Establishes FDA Diagnostics Advisory Committee to provide advice on the development of guidelines for categorizing by risk types of tests and criteria for evaluating the sufficiency of evidence to demonstrate a test is accurate and reliable;
- Authorizes the establishment of registration fee and user fees for IVDP Sponsors.

Status: Not yet introduced